JUL 2 3 2001

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the Entific Medical System's summary for the bilateral fitting of BAHA.

SUBMITTER'S NAME: Entific Medical Systems
ADDRESS: P:O: Box 16024
SE-412 21 Göteborg
Sweden
CONTACT PERSON: Constance Bundy
TELEPHONE NUMBER: 763-574-1976
FAX NUMBER: 763-574-2437
DATE OF SUBMISSION: May 8, 2001

1. **Identification of device**
Proprietary Name: Bilateral fitting of BAHA™
Common Name: Bilateral fitting of Branemark Bone Anchored Hearing Aid
Classification Status: Class II per regulations 21 CFR § 874.3300
Product Codes: LXB

2. **Equivalent devices**
Entific Medical Systems believes the bilateral fitting of BAHA is substantially equivalent regarding intended use to bilateral fitting of air conduction hearing aids(exempt) and has the same technological characteristics as the predicate product, the Branemark Bone Anchored Hearing Aid, K955713.

3. **Description of the Device**
The BAHA is a bone conduction-type hearing aid. Unlike conventional hearing aids, which depend on acoustic coupling through the air, the BAHA is based on a bone conduction technology. Sound is transmitted directly through the bones of the skull to the cochlea, bypassing the middle ear. The BAHA is connected to a fixture pillar, which has been surgically placed in the bone behind the ear.

4. **Intended use**
Bilateral fitting of the bone anchored hearing aid BAHA is intended for patients who suffer from moderate to severe bilateral symmetric conductive hearing losses. Symmetric bone conduction threshods are defined as less than 10dB difference in average or less than 15dB at individual frequencies. Frequencies used to determine average bone conduction thresholds are 0.5, 1, 2, and 4kHz.
Also indicated are patients with mixed hearing loss with average bone conduction thresholds better than 45dB HL. Patients with bone conduction thresholds between 25-45dB HL will be expected to improve, but may not have restored hearing levels to the normal range.

The use of bilateral BAHA is intended to improve binaural hearing, which may improve sound localization and speech recognition.

5. Technological characteristics, comparison to predicate device.

Comparison table

Characteristic	**Air conducted Hearing Aids**	**BAHA – Branemark Bone Anchored Hearing Aid - Unilateral**	**BAHA – Bilateral Fitting**	**S/Eq**
Material	Multiple	Implant: Titanium Abutment Snap: PEEK	Same as BAHA unilateral	Yes
Intended use	Improvement of sound localization and speech perception through bilateral use.	Improvement of hearing through unilateral use.	Improvement of sound localization and speech perception through bilateral use.	Yes
Power requirement	N/A	BAHA Classic 300-Nickel-Metal-Hydride	BAHA Classic 300-Nickel-Metal-Hydride	Yes
Max gain	N/A	BAHA Classic 300 - 33dB	BAHA Classic 300 - 33dB	Yes
Frequency response	N/A	125 Hz – 8 KHz	125 Hz – 8 KHz	Yes
Sterilization and manufacturing processes	N/A	Same	Same	Yes
Manufacturer	N/A	Entific Medical Systems	Entific Medical Systems	
K-number	Exempt	K955713	Pending	

6. Discussion of testing

A clinical study was conducted to establish the benefits of bilateral use, including sound localization, speech perception in quiet and in noise.

7. **Conclusion**

Based on a comparison to the predicate devices, it is the conclusion of Entific Medical Systems that the BAHA for Bilateral fitting is substantially equivalent to devices already on the market, both cleared by and exempt from the 510(k) process and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 2001

Entific Medical Systems, Inc.
C/O Ms. Constance Bundy
C.G. Bundy Associates, Inc.
6740 Riverview Terrace
Minneapolis, MN 55432

Re: K011438
Trade Name: Bilateral fitting of the BRÅNEMARK Bone-Anchored-Hearing Aid
Regulation Number: 21 CFR §874.3300
Regulatory Class: Class II
Product Code: LXB
Dated: May 8, 2001
Received: May 10, 2001

Dear Ms. Bundy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

B. INDICATIONS FOR USE

510(k) Number K011438

Device Name: The BRÅNEMARK Bone-Anchored-Hearing Aid (BAHA™) System.

Indications for Use:

Bilateral fitting of the BAHA is intended for patients who suffer from moderate to severe bilateral symmetric conductive hearing losses. Symmetric bone conduction thresholds are defined as less than 10dB difference in average or less than 15dB at individual frequencies. Frequencies used to determine average bone conduction thresholds are 0.5, 1, 2, and 4kHz.

Also indicated are patients with mixed hearing loss with average bone conduction thresholds better than 45 dB HL.
Patients with bone conduction thresholds between 25-45 dB HL will be expected to improve, but may not have restored hearing levels to the normal range.

The use of bilateral BAHA is intended to improve binaural hearing, which may improve sound localization and speech perception.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

James K. Koch Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011438

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)